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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,842

07/26/2005

Gallus Schechner

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OSTROLENK FABER GERB & SOFFEN  
1180 AVENUE OF THE AMERICAS  
NEW YORK, NY 100368403

EXAMINER

DEES, NIKKI H

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

11/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,842	<b>Applicant(s)</b> SCHECHNER ET AL.	
	<b>Examiner</b> Nikki H. Dees	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 37-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>22 September 2008, 29 October 2008</u> .                      | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-24 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (DE 10063945 A1) in view of Greenberg et al.

(5,980,955). [The published DE 10063945 is priority document for Kropf et al. (US 2003/0219388 A1). The US document is used below as an English language equivalent to the above German document. A translation of the priority document will be provided with a subsequent office action.]

3. Kropf et al. teach a dental adhesive film comprising a poorly soluble calcium salt [0009]. Chewing gums are taught as another means of introducing active ingredients to tooth and gum surfaces [0003]. The slightly water soluble calcium salts are preferably salts of hydroxyapatite or fluoroapatite [0015]. The calcium salts are preferably from 10-300 nm in size, and are in the form of rod-shaped crystals [0016]. The film produced comprises about 1% of the composite material of the invention [0089]. The calcium salt is preferably provided in combination with a protein. Proteins may include casein, collagen, albumin and gelatin [0020], [0059]. The proteins may also function as

surface-modification agents by adsorbing to the nanoparticles of calcium and preventing agglomeration of the particles [0018].

4. Kropf et al. go on to teach sweeteners for use in their invention including sucrose, lactose, fructose [0054]. They also teach intense sweeteners such as aspartame, thaumatin and sodium cyclamate [0054], inclusion of which would result in a substantially sugar-free product.

5. The invention of Kropf et al. may further comprise fluorine compounds such as sodium fluoride or tin fluoride [0047]. The invention may also comprise flavors and other fillers [0049]-[0055].

6. Kropf et al. are silent as to the composition of the particular coating layers of the chewing gum.

7. Greenberg et al. teach a coated chewing gum product wherein the coating contains a poorly water-soluble salt of calcium (Abstract).

8. The coating material of Greenberg et al. may further comprise sweeteners such as dextrose, maltose, erythritol, xylitol, hydrogenated isomaltulose (isomalt) and other polyols alone or in combination. High intensity sweeteners are also taught for use in the invention (col. 5 lines 61-62). Further, there may be layers of different primary coating materials (col. 4 lines 21-32).

9. Greenberg et al. state that each component of the coating may be applied in a single layer, or in a plurality of layers that are the same or different. Preferably, about 30 to 60 layers are applied (col. 7 lines 4-13).

Art Unit: 1794

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the insoluble calcium salt as taught by Kropf et al. in the chewing gum composition of Greenberg et al. in order to result in a chewing gum product containing nanoparticle-sized calcium in a form that has significant residence time in the mouth in order to improve the dental hygiene of the user, or mineralize the enamel or dentine of the user in the presence of the calcium particles. All of the claimed elements were known in the prior art at the time the invention was made. One of ordinary skill could have substituted the nano-sized calcium particle as taught by Kropf et al. for the insoluble calcium salt in the chewing gum invention of Greenberg et al. with the predictable result of a chewing gum containing the nano-sized calcium particles. Undue experimentation would not have been required, and there would have been a reasonable expectation that the resultant chewing gum would have been effective for its intended purpose of delivering the calcium salts to the surface of the teeth and gums.

11. Claims 25-35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (5,980,955) in view of Kropf et al. (DE 10063945 A1). [The published DE 10063945 is priority document for Kropf et al. (US 2003/0219388 A1). The US document is used below as an English language equivalent to the above German document.]

12. Greenberg et al. teach a method for producing a chewing gum comprising coating a gum core with a coating syrup comprising a slightly water-soluble calcium salt (Abstract). The coating syrup may further comprise sweeteners (col. 5 lines 40-56). The chewing gum core is coated by at least one coating step. Preferably, about 30 to

Art Unit: 1794

60 layers are applied (col. 7 lines 4-13). After coating, the core is dried (col. 7 lines 28-36). The gum core may also be coated with a dry powder of sweetener after coating with a liquid syrup (col. 6 lines 63-66). The powder may also comprise calcium carbonate (col. 7 lines 1-3). The calcium salt is taught in an amount preferably from 1.5 to about 5% in the coating layer (col. 2 lines 64-67).

13. Greenberg et al. are silent as to the calcium salt of their invention being apatite, as well as in the nanometer-size range.

14. Kropf et al. teach a poorly water-soluble calcium salt in the nanometer-size range (10-300 nm) [0016]. The calcium may be in the form of hydroxyapatite or fluoroapatite [0015].

15. One of ordinary skill in the art at the time the invention was made would have been able to utilize the nanometer-size calcium particles as taught by Kropf et al. in the method of making chewing gum as taught by Greenberg et al. The calcium of Kropf et al. is poorly-water soluble, as is called for in the invention of Greenberg et al.

Substitution of this calcium would have yielded the predictable result of a chewing gum containing a poorly water-soluble calcium salt. The resultant method would have been expected to produce a chewing gum containing the active remineralizing calcium compound of Kropf et al. without undue experimentation and with a reasonable expectation of success.

***Response to Arguments***

16. Applicant's arguments filed October 29, 2008, have been fully considered but they are not persuasive.

17. Applicant argues (Remarks, pp. 10-11) that as Kropf is directed to dental films and Greenberg is directed to the preparation of chewing gums, the combination of references is not obvious.

18. Kropf teaches dental films for introduction of remineralizing calcium to the teeth. Kropf also states that chewing gums may be used to administer agents to the surface of the tooth as they generally have a long residence time in the mouth [0002 English translation]. Greenberg teaches chewing gums coated with poorly soluble calcium salts.

19. One of ordinary skill in the art at the time the invention was made, being familiar with both methods of making chewing gums and the desirability of making chewing gums that provide a remineralizing benefit would have been able to modify the coating of Greenberg to incorporate the nanoparticulate calcium of Kropf to provide a chewing gum effective to administer the nanoparticulate calcium to the surface of the teeth.

20. Applicant argues repeatedly that the differences in solubility between the calcium salts of the Kropf reference and the calcium salts of the Greenberg reference would preclude the combination of the references.

21. In response it is noted that Greenberg states that his invention may be optimized depending on the particular poorly soluble calcium salt to be used (col. 2 lines 26-34).



The solubilities reported by Greenberg are declared to be “typical” (col. 2 line 56). One of ordinary skill desiring to provide calcium to the surface of the tooth would have recognized chewing gums to be an obvious way to do so. The differences in solubility taught by Kropf (1 g/L at 20°C) and Greenberg (lower limit of about 5 g/L at 10°C) is not considered to represent a significant difference in solubility, as is urged by Applicants. Further, the poorly soluble salt is desirable in Greenberg as one factor to affect crystallization of the coating layers. The artisan, then, could have developed a suitable coating comprising the calcium salts of Kropf without undue experimentation and with the reasonable expectation that the coating with both provide the salts effectively to the surfaces of the teeth, as well as provide an acceptable coating for chewing gums.

22. Applicant argues that the dental film of Kropf is far from the teachings of Greenberg and the claimed invention (Remarks, p. 12).

23. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

24. In this case, Kropf is used to teach the nanoparticles of calcium for use in the invention. It appears that Applicants are using the same slightly water-soluble calcium

salts as taught by Kropf. As noted previously, Kropf clearly states that chewing gums may be used to administer oral health agents to the tooth surface. Greenberg states that his invention may be optimized depending on the particular poorly soluble calcium salt to be used (col. 2 lines 26-34). One of ordinary skill desiring not only to provide calcium to the surface of the tooth would have recognized chewing gums to be an obvious way to do so, and further would have recognized that the coating of the chewing gum with the agent to be delivered

25. Additionally, the coating materials, number of layers, and sweeteners as claimed by Applicants for use in their chewing gum invention are notoriously conventional in the chewing gum art. One of ordinary skill would have been able to modify the particular coatings in order to incorporate the desired poorly soluble calcium salts.

### ***Conclusion***

26. An English translation of DE 10063945 A1 is provided with this Office Action.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1794

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees  
Examiner  
Art Unit 1794

Application/Control Number: 10/528,842  
Art Unit: 1794

Page 10

/Carol Chaney/  
Supervisory Patent Examiner, Art Unit 1794